DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 10-1-04
Publication Date 10-4-04
Certifier R. VEDESMA

Food and Drug Administration

Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Clinical Pharmacology Subcommittee of the Advisory Committee for Pharmaceutical Science.

General Function of the Subcommittee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on November 3, 2004, from 8 a.m. to 5:30 p.m., and on November 4, 2004, from 8 a.m. to 1:30 p.m.

Location: Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD.

Contact Person: Hilda Scharen, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301–827–7001, FAX 301–827–6776, e-mail: *SCHARENH@cder.fda.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572) in the Washington, DC area), code 3014512539. Please call the Information Line for up-to-date information on this meeting.

oc04235

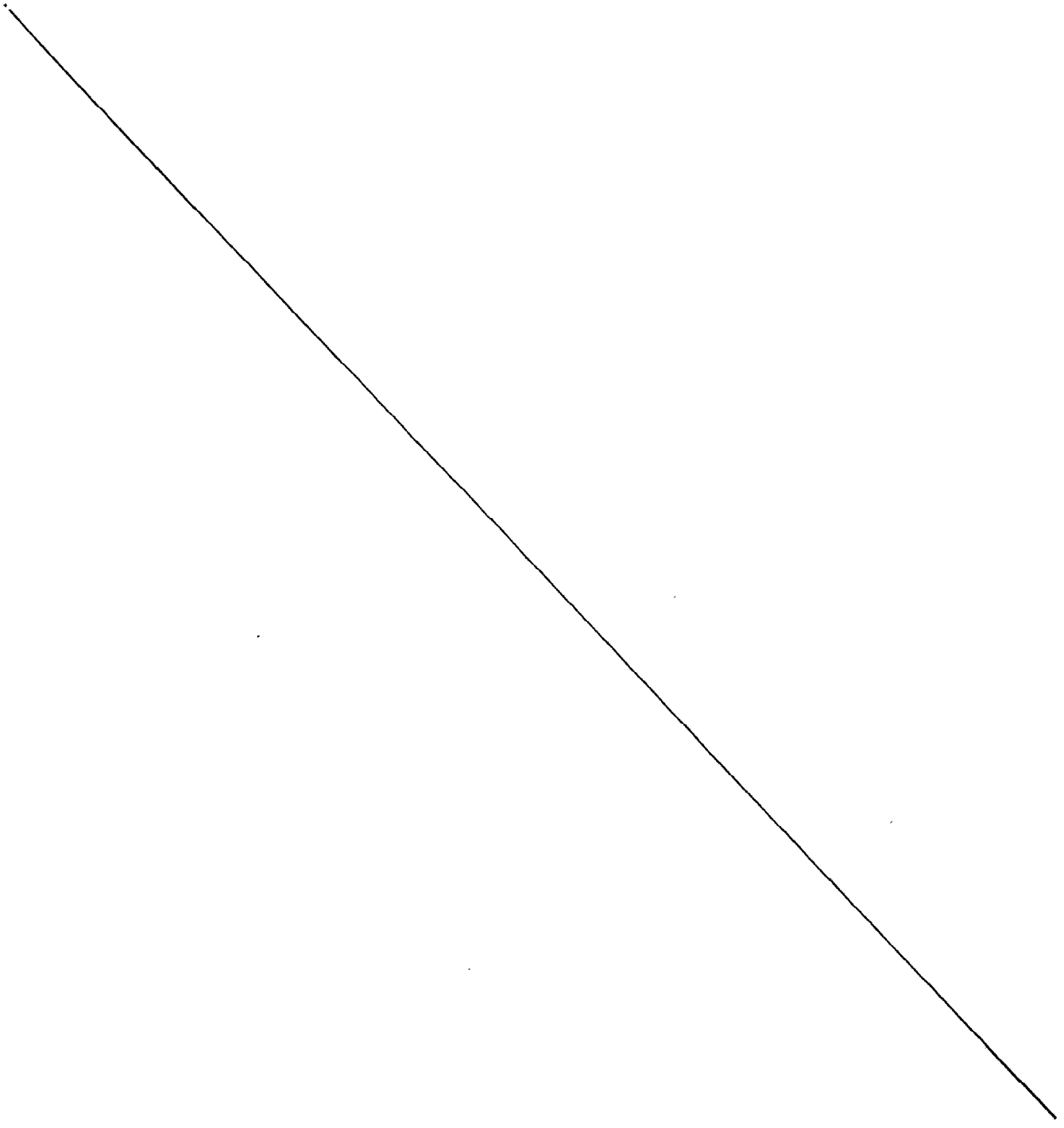
NM1

Agenda: On November 3, 2004, the subcommittee will: (1) Receive topic updates for ongoing FDA activities previously presented to the subcommittee; (2) discuss and provide comments on the evidence for updating labels of approved drugs to include integrating pharmacogenetic, pharmacokinetic, and prognostic biomarkers for the purpose of optimizing therapeutic response and reducing risks of toxicity; and (3) discuss and provide comments on metabolism- and transporter-based drug-drug interactions included as recommendations in a draft guidance for industry being prepared by FDA. On November 4, 2004, the subcommittee will discuss and provide comments on a new critical path project related to general aspects of the transition of biomarkers to surrogate endpoints, with a focus on planning and process, rather than on specific biomarkers or surrogate endpoints.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by October 25, 2004. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1 p.m. on November 3, 2004, and between 1 p.m. and 1:30 p.m. on November 4, 2004. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before October 25, 2004, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Hilda Scharen at least 7 days in advance of the meeting.



Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: Sept 24, 2004

September 24, 2004.

Sheila Dearybury Walcoff

Sheila Dearybury Walcoff,
Associate Commissioner for External Relations.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S